No. 94-372

In the Supreme Court of the United States

OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MARGARET WHITECOTTON, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTIONS PRESENTED

1. Whether, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-11(c)(1)(C)(i), a presumption that a vaccine has caused an injury can be established by evidence that a symptom of the injury occurred shortly after administration of the vaccine, when that injury had already manifested itself prior to administration of the vaccine and the injury did not markedly worsen afterwards.

2. If so, whether the presumption of causation can be rebutted by a showing that an identifiable preexisting condition caused the injury, when the specific cause of that condition is unknown.

PARTIES TO THE PROCEEDING

Petitioner is Donna E. Shalala, the Secretary of Health and Human Services. Respondents are Margaret, Kay and Michael Whitecotton.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-9a) is reported at 17 F.3d 374. The opinion of the United States Claims Court (now the Court of Federal Claims) (Pet. App. 10a-23a) and the decision of the Special Master (Pet. App. 24a-43a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 15, 1994. A petition for rehearing was denied on April 29, 1994. Pet. App. 44a-45a. On July 19, 1994, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 27, 1994 (a Saturday). The petition for a writ of

certiorari was filed on August 29, 1994, and was granted on October 31, 1994. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992), provides, in pertinent part:

§ 300aa-11. Petitions for compensation

* * * * *

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died —

* * * * *

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table[.] * * *

* * * * *

§ 300aa-13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition; and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma

and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

* * * * *

§ 300aa-14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I. DPT * * *

Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:

* * * * *

B. Encephalopathy (or encephalitis) ..... 3 days

* * * * *

(b) Qualifications and aids to interpretation

* * * * *

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a) of this section:

* * * * *

(3) (A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa-11 of this title for a vaccine-

related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

* * * * *

§ 300aa-33. Definitions

For purposes of this part:

* * * * *

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

* * * * *

STATEMENT

1. In 1986, Congress enacted the National Childhood Vaccine Injury Act (Vaccine Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755, codified as amended at 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992). Part 1 of the Act directs the Secretary of Health and Human Services (Secretary) to establish a National Vaccine Program designed "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1; see 42 U.S.C. 300aa-1 to

300aa-6 (1988 & Supp. IV 1992). Part 2 of the Act, at issue here, establishes a National Vaccine Injury Compensation Program (compensation program), administered by the Secretary, "under which compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-10 to 300aa-34 (1988 & Supp. IV 1992).

a. Under the compensation program, compensation for injury or death related to administration of a vaccine prior to the effective date of the Act in 1986 is paid out of appropriations by Congress. 42 U.S.C. 300aa-15(i)(1). Compensation in connection with administration of a vaccine after that date is paid out of the Vaccine Injury Compensation Trust Fund established in the Treasury by 26 U.S.C. 9510 (1988 & Supp. V 1993) and funded by a tax imposed by 26 U.S.C. 4131 on the manufacture of vaccines. See 42 U.S.C. 300aa-15(i)(2); see also 42 U.S.C. 300aa-15 (setting forth elements of compensation available under the program).

The compensation program is designed to afford a fair, informal, and expeditious alternative to tort suits against vaccine manufacturers as a way of securing a monetary recovery on behalf of persons who are alleged to have been injured by the administration of a vaccine. *Schafer* v. *American Cyanamid Co.*, 20 F. 3d 1, 2-3 (1st Cir. 1994); see, *e.g.*, 42 U.S.C. 300aa-12 (1988 & Supp. IV 1992) (describing procedures). Accordingly, in the case of a vaccine administered after the effective date of the Act, no civil action seeking more than $1000 in damages may be brought unless and until the claimant has exhausted the procedures under the Act. 42 U.S.C. 300aa-11(a)(2) (Supp. IV 1992); see also 42 U.S.C. 300aa-16 (1988 & Supp. IV 1992) (limitations of actions); 42 U.S.C. 300aa-21(a) (1988 & Supp. IV 1992) (election by claimant after procedures exhausted). The Act also provides

measures to encourage invocation of the compensation program in connection with claims based on administration of vaccines prior to the effective date of the Act. See, *e.g.*, 42 U.S.C. 300aa-10(b) (declaring it to be ethical obligation of attorney who is consulted about vaccine-related injury to advise individual that compensation may be available under the program); 42 U.S.C. 300aa-10(c) (Supp. IV 1992) (Secretary shall undertake reasonable efforts to inform the public of the availability of the program).

b. A proceeding under the compensation program is initiated by the filing of a petition in the Court of Federal Claims. 42 U.S.C. 300aa-11(a)(1) (Supp. IV 1992). A claimant may establish an entitlement to compensation by relying on the Vaccine Injury Table, which in effect provides for a rebuttable presumption of causation in certain circumstances. See 42 U.S.C. 300aa-14(a) (Supp. IV 1992). The Table identifies vaccines covered by the Act and lists particular injuries, disabilities, illnesses, and conditions after each vaccine. The Table then specifies for each injury, disability, illness, or condition a "[t]ime period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." 42 U.S.C. 300aa-14(a) (Supp. IV 1992).[1] See p. 4, *supra*. The claimant is entitled to a rebuttable presumption of causation if the special master or court finds on the record as a whole that the claimant has shown by a preponderance of the evidence that a child "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine [the child received] * * *, and the first symptom or manifestation

[1] The Secretary has authority to promulgate regulations to modify the Vaccine Injury Table. See 42 U.S.C. 300aa-14(c).

of the onset or of the significant aggravation of any such illness, disability, injury, or condition * * * occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." 42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1) (A) (1988 & Supp. IV 1992).

The Secretary may rebut the presumption of causation and defeat the claim for compensation if she shows by a preponderance of the evidence that the illness, disability, injury, or condition "is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. 300aa-13(a)(1)(B) (1988 & Supp. IV 1992). The term "factors unrelated to the administration of the vaccine" does not, however, include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. 300aa-13(a)(2)(A).

If a child suffers from an injury that is not listed in the Table—or if the child suffers from an injury listed in the Table, but the first symptom or manifestation of the injury did not occur within the Table's time limits—recovery is not altogether precluded. Rather, in those circumstances, the claimant must prove that the vaccine caused the child's condition without the benefit of a rebuttable presumption. 42 U.S.C. 300aa-11(c)(1)(C)(ii).

c. Cases under the compensation program are adjudicated, in the first instance, by a special master. 42 U.S.C. 300aa-12(d)(3) (Supp. IV 1992). On motion by a party, the Court of Federal Claims will review the special master's decision. The court may either uphold the decision, or "set aside any findings of fact or conclusion of law * * * found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. 300aa-12(e)(2)(B)

(Supp. IV 1992). The decision of the Court of Federal Claims is subject to review in the United States Court of Appeals for the Federal Circuit. 42 U.S.C. 300aa-12(f) (Supp. IV 1992).

After judgment is entered by the Court of Federal Claims (or, if an appeal is taken, after the appellate court's mandate is issued), the petitioner who filed the petition under Section 300aa-11 must, within 90 days, file an election in writing with the clerk of the Court of Federal Claims to accept the judgment awarding or denying compensation, or to file a civil action for damages for the injury or death. If an election is not filed within 90 days, the petitioner is deemed to have accepted the judgment. 42 U.S.C. 300aa-21(a) (1988 & Supp. IV 1992).[2]

2. Respondent Margaret (Maggie) Whitecotton was born on April 22, 1975, with a head size in the second percentile, more than two standard deviations below the norm for a child of the same sex and age. Pet. App. 32a-33a. Maggie's head size remained at the second percentile through her first three months of age, but then fell below the second percentile. *Id.* at 33a-34a. The head size of a child is "indicative of the size of the brain." *Id.* at 33a. Children with particularly small heads have a condition known as microcephaly, which is most commonly defined as a head size two standard deviations below the norm for a child of the same sex and age. *Id.* at 32a.

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[2] The Act also prescribes standards of responsibility for manufacturers in any civil action filed with respect to administration of a vaccine after the effective date of the Act, 42 U.S.C. 300aa-22, and prescribes stages for the conduct of the trial in such a civil action and limitations on the availability of punitive damages, 42 U.S.C. 300aa-23 (1988 & Supp. IV 1992).

On August 18, 1975, when Maggie was nearly four months old, she received her third DPT vaccination. After administration of the vaccine, Maggie suffered a series of brief seizures. Pet. App. 27a. She was hospitalized, but subsequently discharged after a neurological examination indicated that her condition was normal and that she had suffered no apparent ill effects from the seizures. *Id.* at 40a. Her treating physicians also decided not to administer any anticonvulsive medication. *Id.* at 30a. The discharge summary diagnosed Maggie as having microcephaly and as having experienced postimmunization encephalopathy with seizures. *Ibid.* The discharge summary also noted the opinion of one treating physician that "children with microcephaly and some brain damage [are] unusually susceptible to this vaccine." *Ibid.*

There was no dramatic change in Maggie's condition following her release. Symptoms of neurological damage gradually appeared, however. Pet. App. 41a-42a. Currently, Maggie is "severely disabled both mentally and physically." *Id.* at 37a. She has cerebral palsy, hip and joint problems, and cannot communicate verbally. *Ibid.* She is, "for all practical purposes, totally dependent on others for her needs." *Ibid.* Maggie had several seizures in the five years following her third DPT vaccination, but has not had any seizures in recent years. *Id.* at 28a-30a.

3. On August 2, 1990, Maggie's parents, who are also respondents, applied for compensation under the Vaccine Act. Pet. App. 2a. They alleged that Maggie had suffered an "encephalopathy" as a result of her third DPT vaccination. *Ibid.* As noted above, an encephalopathy is one of the injuries listed in the Table in connection with the DPT vaccine. "Encephalopathy" is defined as "any significant acquired abnormality of, or injury to, or

impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A). To trigger the presumption of causation under the Table, the first symptom or manifestation of the onset or significant aggravation of an encephalopathy must occur within three days of the administration of the vaccine. 42 U.S.C. 300aa-14(a) (Supp. IV 1992). Maggie's parents alleged that Maggie's post-vaccination seizures were such a manifestation.

a. A special master denied compensation. Pet. App. 24a-43a. The special master adopted the most commonly accepted definition of microcephaly, namely a head size smaller than two standard deviations below the mean for a child of the same sex and age. By that definition, the special master concluded, a child whose head size is at the second percentile is microcephalic, "since the cutoff for two standard deviations is above the second percentile." Pet. App. 32a; see also *id.* at 20a (Claims Court decision). In this case, the special master noted that Maggie's head size was at the second percentile at birth and remained on the second percentile curve through three months of age, but had dropped below that curve by August 20, when she was examined in the hospital after the vaccine was administered. *Id.* at 33a. Based on that evidence, the special master found "that Maggie was at least borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot on August 18, 1975." *Id.* at 32a-33a.

The special master was persuaded by the evidence concerning Maggie's head size and the testimony of neurologists that "Maggie had suffered an encephalopathy sometime prior to the administration of the DPT vaccine on August 18, 1975." Pet. App. 33a. He cited the testimony of the government's expert, who believed that Maggie's head size indicated that she suffered brain injury prior to birth. *Id.* at 34a. The special master also

relied on respondents' expert, who testified that "[s]omething was clearly happening to the child before [the DPT vaccination]" (*id.* at 33a), and who stated in his report that the growth of Maggie's head had fallen below the normal curve, which "implie[d] a post-partum injury to the brain, at or near three months of age" (*id.* at 34a). On that record, the special master found that "[w]hether the injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975." *Ibid.* The special master therefore concluded that Maggie's "original encephalopathy was not a Table injury which followed the August 18 DPT shot." *Ibid.*

The special master also determined that the seizures that had occurred within the three-day statutory period after administration of the vaccine did not significantly aggravate Maggie's preexisting encephalopathy. Pet. App. 34a-43a. The special master found that in Maggie's early months, there were only hints, apart from her small head size, that she might have suffered brain damage. *Id.* at 36a. She rolled over from her stomach to her back at two weeks of age, which could be a sign of spasticity, and she had difficulty swallowing from birth, which could be a sign of mental retardation and cerebral palsy. *Id.* at 36a-37a. The special master found, however, that the absence of obvious symptoms of neurological damage in the early months of life was not atypical for a child with microcephaly. He noted that neurological problems often do not become obvious until a child matures to the point where developmental milestones (such as walking or talking) are missed or delayed. *Id.* at 37a. For example, cerebral palsy typically becomes evident between six months and one year of age. *Id.* at 38a. Mental retardation may not become evident until much later. *Ibid.* The special master determined that

there was more than a 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone. *Ibid.*

The special master further found that the DPT vaccination "may have caused a temporary encephalopathy evidenced by transient seizure activity, but the seizures did not continue and there was no dramatic turn for the worse in [Maggie's] condition indicating a permanent aggravation of her brain disorder." Pet. App. 42a. Rather, the special master explained, as Maggie "matured neurologically, the complications of whatever caused her microcephaly gradually manifested themselves, just as they do in a typical case involving congenital brain damage." *Ibid.* Accordingly, the special master found "no basis for implicating the vaccine as the cause of any aspect of [Maggie's] present condition." *Id.* at 42a-43a.

The special master issued formal findings of fact that were consistent with his analysis of the record evidence. Thus, the special master found that Maggie "was born * * * with a brain disorder evidenced by microcephaly which became more pronounced by the age of four months," that she "suffered transient seizure activity within three days following the administration of the DPT vaccine," that she "did not suffer a permanent encephalopathy within three days following the said administration of DPT vaccine," and that "[n]o significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine." Pet. App. 43a.[3]

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[3] Although respondents' petition for compensation alleged that Maggie suffered from an encephalopathy, respondents asserted at the hearing that Maggie also suffered from a residual seizure disorder. Pet. App. 26a n.2. The special master found that Maggie did not suffer from such a disorder, *id.* at 27a-30a, 42a, and the Claims Court sustained that finding, *id.* at 16a-19a. The court of appeals did not address that issue, and it is not involved here.

b. The United States Claims Court (now the Court of Federal Claims) overruled respondents' objections to the special master's decision and entered judgment for the Secretary. Pet. App. 10a-23a. The court concluded that there was sufficient evidence to support the special master's finding that Maggie was microcephalic before she received her third DPT vaccination, *id.* at 19a-21a, noting that "Maggie's preexisting injury precluded the vaccination from being the cause of the encephalopathy," *id.* at 21a. The court also found sufficient evidence to support the special master's finding that the seizures that had occurred within the three-day statutory period after administration of the vaccine were not an indication that the preexisting encephalopathy had been significantly aggravated by the vaccine. *Id.* at 23a. The court pointed out that "[t]here is simply no evidence that these transient seizures were a sign of permanent brain damage." *Ibid.* The court also cited evidence indicating that Maggie's "entire clinical history is typical for a person with a condition similar to [Maggie's] who did not have vaccine complications." *Ibid.*

c. The court of appeals reversed the judgment of the Claims Court and remanded for an award of compensation. Pet. App. 1a-9a. The court of appeals held that respondents' showing that Maggie had suffered seizures within three days following administration of the vaccine was sufficient to establish a presumption that the vaccine had caused the onset of an encephalopathy. *Id.* at 5a-7a. The court recognized that 42 U.S.C. 300aa-11(c)(1)(C)(i) requires a claimant to show that the first manifestation of any injury occurred after

administration of the vaccine. *Id.* at 5a. The court reasoned, however, that "the Table language [in 42 U.S.C. 300aa-14(a)] is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur." *Id.* at 5a.

The court then held that the Secretary could not rely on Maggie's preexisting microcephaly to show that her current condition was caused by a "factor unrelated" to the vaccine. Pet. App. 7a-8a. The court did not disturb the special master's findings that Maggie "was microcephalic before she received the suspect vaccine," and that her "microcephaly marked [her] as a child likely to experience developmental problems." *Id.* at 8a. And the court acknowledged that, "[l]ogically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injury." *Ibid.* Nonetheless, the court held that Maggie's microcephaly was not a "factor unrelated" to administration of the vaccine within the meaning of the Vaccine Act. *Id.* at 6a. Relying on its decision in *Koston* v. *Secretary, Dep't of HHS*, 974 F.2d 157, 160-161 (Fed. Cir. 1992), the court concluded that Maggie's microcephaly was "idiopathic" because, although it was preexisting, its specific cause could not be identified. Pet. App. 7a-8a.[4]

[4] The court of appeals denied the Secretary's petition for rehearing and suggestion for rehearing en banc. Pet. App. 44a-45a.

SUMMARY OF ARGUMENT

The court of appeals has interpreted the Vaccine Act to require compensation in circumstances in which a child's condition logically could not have been caused by a vaccine. The court arrived at that result by misinterpreting two provisions of the Act.

A. First, the court erred in its construction of 42 U.S.C. 300aa-11(c)(1)(C)(i), which creates a presumption of causation when a claimant can show that "the first symptom or manifestation of the onset or of the significant aggravation" of the child's condition occurred within the time period after administration of the vaccine set forth in the Act. The court held that the phrase "first symptom or manifestation of the onset" means that a claimant is entitled to a presumption of causation as long as *any* symptom or manifestation of an underlying injury or condition occurred within the statutory period. In the court's view, the claimant does not have to show that there was no preexisting symptom or manifestation of that condition.

That construction is at odds with the plain meaning of the statutory text. When an injury or condition has manifested itself prior to administration of the vaccine, a manifestation after administration cannot be the "first." And when an injury or condition had its start prior to administration of the vaccine, any manifestation that occurs after that time cannot be a manifestation of the "onset."

The court of appeals' interpretation also renders superfluous the statutory text creating a presumption of causation when the first symptom or manifestation of a "significant aggravation" of a preexisting condition occurs within the statutory period after administration of the vaccine. If a presumption of causation arises

whenever any symptom happens to occur within the Table period, there would never be a need for a claimant to establish a significant aggravation of a preexisting condition. Implicit in Congress's decision to authorize significant aggravation as a separate ground for recovery is that there cannot be a presumption of causation when a condition that manifested itself prior to administration of the vaccine did not get markedly worse afterwards.

This interpretation of the statutory scheme also is the most logical. Presumptions are generally created when there is at least some likelihood that the presumption is in fact accurate. When a condition for which a claimant seeks recovery had already manifested itself prior to administration of the vaccine and the condition did not markedly worsen afterwards, there is no realistic possibility that the vaccine caused the condition.

The court of appeals, while recognizing that the language in Section 300aa-11(c)(1)(C)(i) did not support its interpretation of the Act, held that the language in the heading to the Table in 42 U.S.C. 300aa-14(a) (Supp. IV 1992) did. There is, however, no relevant distinction between the two Sections. Both provide that the symptom or manifestation in the statutory period must be "the *first* symptom or manifestation of the *onset* or of the significant aggravation" of the condition (emphasis added). Moreover, if there were a difference between the two, Section 300aa-11(c)(1)(C)(i) would take precedence, since that Section formally sets forth the elements that a claimant must establish. The language in Section 300aa-14(a) relied upon by the court of appeals is simply a heading that summarizes the requirements for a presumption in shorthand form. The other statutory provisions relied upon by the court of appeals merely articulate the details of the statutory scheme or fashion

special standards for its application in particular circumstances; they do not undermine the clear import of Section 300aa-11(c)(1)(C)(i).

B. The court of appeals also erred in holding that the Secretary could not rely on Maggie's microcephaly to rebut a prima facie case of causation because her microcephaly is, in the court's view, "idiopathic." Although the Act excludes "idiopathic" factors from the "factors unrelated to the administration of the vaccine" that may rebut a prima facie case, the Secretary did not rely on such a factor here.

Idiopathic means "of unknown cause." Accordingly, in order to rebut the presumption, the Secretary cannot rely exclusively on medical evidence showing that there is no known cause of the child's injury or on evidence showing that there is no established relationship between the vaccine and the child's injury. The Secretary must be able to point to an identifiable condition as an explanation for the claimant's injury. Here, the Secretary did point to a specific, preexisting condition—microcephaly—to explain Maggie's current condition. Because microcephaly is sufficiently well-defined, and because it logically eliminates the vaccine as the cause of Maggie's injuries, it is non-idiopathic within the meaning of the Vaccine Act.

The court of appeals held that the Secretary was relying on an "idiopathic" factor because the Secretary could not in turn identify the specific cause of Maggie's microcephaly. It is true that the cause of Maggie's preexisting condition is not fully understood. But that is almost always true in medicine. Congress could not have intended the term "idiopathic" to be applied at that level of generality, since to do so might effectively preclude the Secretary from ever rebutting a prima facie case. Thus, as the legislative history confirms, the court of

appeals took the requirement that an unrelated factor must be non-idiopathic one step further back than Congress intended.

The court of appeals' interpretation also would lead to consequences that Congress could not have intended. For example, under the court of appeals' interpretation, if the Secretary could prove that a child had only a partial brain at birth and that such a condition inevitably results in the kinds of injuries that the child suffers, a prima facie case could not be rebutted unless the Secretary could also establish what had caused the child to have a partial brain. Since Congress could not have intended to permit compensation in circumstances in which the evidence shows that a preexisting condition and not the vaccine caused the child's injuries, the court of appeals' interpretation of the term "idiopathic" should be rejected.

ARGUMENT

THE COURT OF APPEALS ERRED IN HOLDING THAT THE VACCINE ACT AUTHORIZES COMPENSATION WHEN THE CHILD'S INJURY FIRST MANIFESTED ITSELF PRIOR TO ADMINISTRATION OF THE VACCINE

The court of appeals has interpreted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) to require compensation in circumstances in which logic dictates that a child's condition was not caused by the vaccine. The court arrived at that result by misinterpreting two provisions of the Act. Specifically, the court improperly construed 42 U.S.C. 300aa-11(c)(1)(C)(i), which sets forth the elements that a claimant must prove to establish a presumption that the vaccine has caused his or her condition, and 42 U.S.C. 300aa-13(a)(1)(B) (1988 & Supp. IV 1992), which sets forth what the Secretary must show to rebut that statutory

presumption. Each of those errors independently requires reversal of the judgment below.

A. Proof That A Symptom Of A Condition Occurred Within The Table Period After Administration Of A Vaccine Does Not Create A Presumption That The Vaccine Caused The Condition When The Condition Had Already Manifested Itself Prior To Administration Of The Vaccine

The Vaccine Act provides that a rebuttable presumption of causation exists when a claimant shows by a preponderance of the evidence that a child

> sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a specified] vaccine * * *, and the first symptom or manifestation of the onset of or the significant aggravation of any such illness, disability, injury, or condition * * * occurred within the time period after vaccine administration set for in the Vaccine Injury Table.

42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1)(A) (1988 & Supp. IV 1992). That statutory language creates a presumption of causation in two kinds of cases: those in which the claimant shows that the child first began to suffer from an injury or condition after administration of the vaccine, and those in which the claimant shows that the child suffered from a Table injury or condition prior to administration of the vaccine, but that it markedly worsened thereafter.

In this case, the special master carefully examined each of those possibilities. The special master found that Maggie's head size indicated that she had already suffered an encephalopathy before she received her third DPT vaccination. Pet. App. 30a-34a. The special master

also found that the seizures that Maggie experienced after administration of her third DPT vaccine did not significantly aggravate that preexisting condition. *Id.* at 34a-43a. The special master therefore properly concluded that respondents could not rely on the presumption of causation established by Section 300aa-11(c)(1)(C)(i).

The court of appeals did not disturb the special master's findings that Maggie suffered from an encephalopathy before she received her third administration of the DPT vaccine and that her condition did not markedly deteriorate afterwards. The court nonetheless held that there was a presumption that the DPT vaccine caused Maggie's current condition. It reasoned that the statutory phrase "first symptom or manifestation of the onset" means that a claimant is entitled to a presumption of causation as long as *any* symptom or manifestation of an underlying injury or condition happened to occur within the Table period. Pet. App. 5a-7a. That holding is incorrect for several reasons.

1. First, the court's interpretation cannot be reconciled with the plain meaning of the statutory text. The term "first" means "before all others," and the term "onset" means "a beginning or start." *The Random House Dictionary of the English Language* 723, 1354 (2d ed. 1987); see also *Webster's Third New International Dictionary* 856, 1577 (1986) (defining "first" as "being number one in a countable series," and "onset" as "beginning, commencement, start"); 5 *The Oxford English Dictionary* 957 (2d ed. 1989) (defining "first" as "[p]rior to all others in occurrence"); 10 *The Oxford English Dictionary*, *supra*, at 821 (defining "onset" as "beginning, commencement, start"). When an injury or condition has manifested itself prior to administration of a vaccine, a manifestation that occurs after administration cannot be the "first." And when an injury or condition had its start prior to administration of a vaccine, any manifestation that occurs after administration cannot be a manifestation of the "onset." Simply put, the phrase "first symptom or manifestation of the onset" cannot mean a *further* symptom of a *preexisting* injury.

In interpreting the meaning of legislation, "courts must presume that a legislature says in a statute what it means and means in a statute what it says." *Connecticut Nat'l Bank* v. *Germain*, 112 S. Ct. 1146, 1149 (1992). Because the court of appeals' interpretation is at odds with the statutory text, it must be rejected.

2. The court of appeals' interpretation also violates the principle that "a statute should be interpreted so as not to render one part inoperative," *Department of Revenue of Oregon* v. *ACF Industries, Inc.*, 114 S. Ct. 843, 848 (1994), because it fails to give any meaning to the statutory text creating a presumption of causation when the first symptom or manifestation of a "significant aggravation" of an injury or condition occurs within the statutory period after the administration of a vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(i). Under the Act, "significant aggravation" means "any change for the worse in a *preexisting condition* which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. 300aa-33(4) (emphasis added). If, as the court of appeals concluded, a presumption of causation arises whenever any symptom occurs within the statutory period, there would never be a need for a claimant to establish a significant aggravation of a preexisting condition. As one special master has recently explained, under the court of appeals' interpretation, significant aggravation "need no longer be referenced in the resolution of any Table cases."

Cepeda v. *Secretary of the Dep't of HHS*, No. 90-2664V (Fed. Cl. July 12, 1994), slip op. 2.

Congress could not have intended for the significant aggravation presumption to be superfluous. Rather, as the definition of "significant aggravation" makes clear, that presumption must have been designed to cover the cases in which a Table condition was "preexisting" and had manifested itself prior to administration of the vaccine. Implicit in Congress's decision to authorize significant aggravation as a separate ground for recovery is that there cannot be a presumption of causation or an award of compensation where, as here, a condition that manifested itself prior to administration of the vaccine did *not* get markedly worse afterwards.

The legislative history to the Vaccine Act confirms that natural reading of the statutory text. As explained in the House Report, the Act "does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g. a child with monthly seizures who, after vaccination, has seizures on a daily basis)." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 14-16 (1986). The court of appeals' decision fails to give effect to that congressional intent.

3. Had Congress intended to create a presumption like the one imposed by the court of appeals, it surely would have done so in far simpler terms. Instead of providing that a claimant must show that the first symptom or manifestation of the onset or significant aggravation of the condition occurred within the statutory period, Congress could simply have provided that the claimant must show that "a symptom or manifestation of the condition occurred within the time

period after vaccine administration set forth in the Vaccine Injury Table." The language Congress chose shows that it decided to create a presumption where the claimant could show not only that a symptom of the condition occurred in the statutory period, but also either that there was no symptom or manifestation of the condition prior to administration of the vaccine, or, if there was, that there was a marked deterioration in that preexisting condition after administration of the vaccine.

That choice by Congress is a logical one. When a claimant can show that the first symptom of onset or significant aggravation of a condition occurred within a short time after administration of a vaccine, there is at least a substantial likelihood that the vaccine might have caused that condition. Creating a presumption of causation in such circumstances is therefore consistent with the manner in which presumptions are recognized as a general matter. See *NLRB* v. *Baptist Hosp., Inc.*, 442 U.S. 773, 787 (1979) (presumption appropriate where there is "a sound factual connection between the proved and inferred facts"); *International Bhd. of Teamsters* v. *United States*, 431 U.S. 324, 359 n.45 (1977) (proof that employer has engaged in a policy of discrimination creates sufficient likelihood that employer has engaged in discrimination in an individual case to shift the burden of proof); *Price Waterhouse* v. *Hopkins*, 490 U.S. 228, 262-266 (1989) (O'Connor, J., concurring in the judgment) (proof that discrimination is a substantial factor in a decision creates sufficient likelihood that discrimination is the but-for cause to shift burden of proof). When a condition for which a claimant seeks recovery has already manifested itself prior to administration of the vaccine and the condition did not markedly worsen afterwards, however, there is no realistic possibility that the vaccine caused the condition. The creation of a

presumption of causation in those circumstances therefore would make no sense.

4. The court of appeals appeared to recognize that the phrase "first symptom or manifestation of the onset" in Section 300aa-11(c)(1)(C)(i) requires a showing that the first of all symptoms of the condition occurred after administration of the vaccine. Pet. App. 5a. The court concluded, however, that the language in Section 300aa-14(a) that serves as a heading for the statutory time periods for Table injuries dictates a different conclusion. Pet. App. 5a. That heading reads: "Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." 42 U.S.C. 300aa-14(a) (Supp. IV 1992). According to the court of appeals, Section 300aa-14(a), unlike Section 300aa-11(c)(1)(C)(i), provides that "the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur." Pet. App. 5a.

There is, however, no relevant distinction between Section 300aa-11(c)(1)(C)(i) and Section 300aa-14(a). Both provide that the symptom or manifestation in the Table period must be "the *first* symptom or manifestation of the *onset* or of the significant aggravation" of the condition (emphasis added), not simply "a" or "any" symptom or manifestation of the condition. If there were a difference between the two Sections, however, Section 300aa-11(c)(1)(C)(i) should take precedence over Section 300aa-14(a), not the other way around. The language in Section 300aa-14(a) cited by the court of appeals is simply a heading that summarizes the rule in shorthand form. In contrast, Section 300aa-11(c)(1)(C)(i) formally sets forth the elements that a claimant must establish to trigger the statutory presumption of causation. See 42 U.S.C. 300aa-13 (1988 & Supp. IV 1992).

The court of appeals also purported to find support for its interpretation in the manner in which residual seizure disorders are addressed in the "Qualification and aids to interpretation," which appears in subsection (b) of Section 300aa-14, following the Table. There, the Act provides that a residual seizure disorder may be found if the claimant "did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved." 42 U.S.C. 300aa-14(b)(2). The court of appeals reasoned that, because the Act places no such limitation with respect to encephalopathies, Congress must not have intended to require claimants to show that there was no preexisting symptom of that injury or condition. Pet. App. 5a-6a. The special provision on seizure disorders was necessary, however, because seizures accompanied by high fevers may not be symptomatic of a seizure disorder. To avoid any uncertainty about whether the existence of pre-vaccination seizures accompanied by high fevers would preclude a showing of post-vaccination onset, Congress made clear that they would not. Thus, the provision does not demonstrate that Congress intended to require claimants to show the absence of prior symptoms or manifestations in residual seizure disorder cases, but not in others. Instead, it clarifies how the general statutory requirement—that a claimant must show that a manifestation that occurred within the statutory period was the first such manifestation—should be applied in the special circumstances of alleged residual seizure disorders.

Finally, the court of appeals attributed significance to the provision in the Act that permits a prima facie case to be defeated upon proof by a preponderance of the evidence that the injury or condition was due to "factors

unrelated to the administration of the vaccine," 42 U.S.C. 300aa-13(a)(1)(B) (1988 & Supp. IV 1992), a term that may include "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances," 42 U.S.C. 300aa-13(a)(2)(B). According to the court, "[i]t would make no sense to allow proof by the Secretary of birth trauma as a factor unrelated if the petitioner were required to prove that no such preexisting injury occurred as an element of the Table case." Pet. App. 6a. That reasoning is flawed.

There may well be cases in which a child has a preexisting condition, but no signs of that condition appeared prior to administration of the vaccine. There may also be cases in which signs of the condition appeared, but they were unobserved or unrecorded. In such circumstances, the claimant may establish a prima facie case of causation by showing that the first symptom or manifestation of the condition occurred within the Table period. The "factors unrelated" provision serves the distinct purpose of permitting the Secretary to rebut that prima facie case by showing that, even though the record does not establish that there was a prior symptom or manifestation of the injury or condition, it nonetheless is due to an unrelated *factor*, such as birth trauma. See *Knudsen* v. *Secretary of Dep't of HHS*, No. 93-5107 (Fed. Cir. Sept. 9, 1994), slip op. 6-7. The "factors unrelated" provision is therefore entirely compatible with the requirement that the claimant must show that a symptom or manifestation that occurred within the Table period was the "first" such symptom or manifestation of the "onset" of the injury or condition.

5. In sum, in order to establish a presumption of causation, it is not enough for a claimant to show that a symptom or manifestation of a Table condition happened

to occur in the statutory period. The claimant must also establish either that there was no previous symptom or manifestation of that condition, or that the preexisting condition markedly worsened after administration of the vaccine.

B. The Secretary May Rebut A Prima Facie Case Of Causation By Proving That An Identified Preexisting Condition Caused The Injury, Even Though The Specific Cause Of That Condition Is Itself Unknown

The court of appeals likewise erred in holding that the Secretary could not rely on Maggie's preexisting microcephaly to rebut a prima face case of causation. The Act expressly provides that compensation shall be awarded if the special master or court finds that the petitioner has demonstrated by a preponderance of the evidence the matters necessary to recover (including the predicate circumstances for invoking the rebuttable presumption created by the Table), and "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300-13(a)(1)(A) and (B) (1988 & Supp. IV 1992). The latter clause sets out the basis for the Secretary to rebut the presumption of causation.

The special master found that Maggie's microcephaly was unrelated to administration of the vaccine and that it marked her as a child likely to experience the very developmental problems that she ultimately encountered as she matured. Pet. App. 42a-43a. In particular, the special master found that "there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone." *Id.* at 38a. Those findings were sufficient to support the conclusion

that Maggie's current condition is due to "factors unrelated to the administration of the vaccine."

The court of appeals did not disturb the special master's findings, and it acknowledged that, "[l]ogically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injuries." Pet. App. 8a. The court nonetheless held that the Secretary had not established a "factors unrelated" defense because, in its view, Maggie's microcephaly was, in turn, "idiopathic." *Id.* at 8a-9a. That holding is in error. The Act provides that the term "factors unrelated to the administration of the vaccine" "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition," 42 U.S.C. 300aa-13(a)(2)(A), and it thereby precludes the Secretary from relying on an "idiopathic" factor to rebut a prima facie case of causation. But the Secretary did not rely on such a factor here.

1. Medical dictionaries uniformly define "idiopathic" as "of unknown cause." *International Dictionary of Medicine and Biology* 1398 (1976); *Stedman's Medical Dictionary* 762 (25th ed. 1990); *Dorland's Illustrated Medical Dictionary* 815 (27th ed. 1988); *The American Medical Association Encyclopedia of Medicine* 566 (1989). The core of what Congress was attempting to preclude by ruling out reliance on "idiopathic" factors is apparent from that definition. The Secretary could not attempt to rebut a prima facie case by relying on a statement from an expert such as: "I have no idea what caused the injury, but it could not have been the vaccine."

That statutory protection for the claimant is important. There are medical studies that show that the overall frequency of certain identified conditions in children who receive the DPT vaccine is the same as it

is in children who do not receive the vaccine. See *Grant* v. *Secretary of Dep't of HHS*, 956 F.2d 1144, 1148-1149 (Fed. Cir. 1992). Outside the context of the Vaccine Act, such studies have been found to be sufficient by themselves to defeat a finding of causation. See, *e.g.*, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823, 830 (D.C. Cir. 1988), cert. denied, 493 U.S. 882 (1989). Because the Vaccine Act excludes reliance on "idiopathic" or "unknown" factors from consideration as "factors unrelated to the administration of the vaccine," the Secretary could not rely on such studies alone to rebut a prima facie case. Similarly, the Secretary could not attempt to rebut a prima facie case by relying on a condition that has no medical meaning or significance other than to identify a situation in which the cause of the injury is unknown. For example, the Secretary could not attempt to rebut a prima facie case of a vaccine-related death by proving that a child died from sudden infant death syndrome (SIDS) because SIDS "is not an illness or injury, but an idiopathic diagnosis used to describe the otherwise unexplained death of an infant." *Hodges* v. *Secretary of Dep't of HHS*, 9 F.3d 958, 963 (Fed. Cir. 1993) (internal quotation marks omitted).

What these examples have in common is the absence of any identifiable condition as an explanation for the person's injuries. When the Secretary is unable to point to such an identifiable condition, the Act requires that the claimant receive the benefit of the doubt on the issue of causation, even though it is unclear whether the vaccine actually caused the injury. Here, however, the Secretary *did* identify a specific, preexisting condition—microcephaly—to explain Maggie's brain injury. Because that condition is sufficiently well-defined, and because it logically eliminated the vaccine as the cause

of Maggie's current injuries, it is non-idiopathic within the meaning of the Vaccine Act.

2. The court of appeals nonetheless concluded that the Secretary was relying on an "idiopathic" factor because the Secretary could not in turn identify the cause of Maggie's preexisting microcephaly. Pet. App. 7a-8a. It is true that the cause of Maggie's underlying condition is not fully understood and that it could therefore be termed "idiopathic" in that broader sense. In medicine, however, the cause of an event is almost never fully understood; there is almost always more to be learned. Congress could not have intended the term "idiopathic" to be applied at that level of generality, however, since to do so might effectively preclude the Secretary from ever rebutting a prima facie case.

The court of appeals lost sight of the fact that the term "idiopathic" is used in the Act for a specific purpose: to limit and define the term "factors unrelated to the administration of the vaccine," which defeats a showing of causation under the Act. The term should be construed with that purpose in mind, and thereby with reference to the degree of relatedness and possible causal nexus between the child's current injury or condition and the "factor" to which the injury or condition is (according to the Secretary's evidence) "due." When the term "idiopathic" is thus read in the context of the Act as a whole, *Brown* v. *Gardner*, No. 93-1128 (Dec. 12, 1994), slip op. 3, it is clear that the court of appeals took the requirement that an unrelated factor must be non-idiopathic one step further back than Congress intended. The Act gives the claimant the benefit of the doubt in cases in which the Secretary cannot point to any identifiable condition that justifies elimination of the vaccine as the cause of the injury or condition. It does not require compensation in circumstances in which the Secretary can point to a specific condition that *does* logically eliminate the vaccine as the cause of the child's current injury, simply because the cause of that specific condition is, in turn, unknown.

The legislative history supports that reading of the statutory text. The House Report states that "factors unrelated to the administration of the vaccine" cannot include "speculative or hypothetical matters or explanations." H.R. Rep. No. 908, *supra*, at 18. It makes clear, however, that the Secretary may prevail by relying on "other, defined illnesses or factors." *Ibid.*

3. The court of appeals' broader definition of "idiopathic" leads to consequences that Congress could not have intended. The Federal Circuit's previous decision in *Koston* v. *Secretary, Dep't of HHS*, 974 F.2d 157 (1992), is illustrative. There, the Secretary introduced evidence that the child's condition was caused by Rett Syndrome, a condition manifested by mental regression and peculiar behavioral symptoms. *Id.* at 160-161. Even though the Secretary could establish that this condition is always present from birth and therefore logically eliminated the vaccine as the cause of the child's condition, the court held that it was idiopathic (and therefore could not be regarded as a "factor unrelated to the administration of the vaccine") because medical science had not yet established the specific cause of Rett Syndrome. *Ibid.*

Similarly, under the court of appeals' interpretation, even if the Secretary could prove that a child had only a partial brain at birth and that such a condition invariably results in the kind of injury or disability from which the child suffers, a prima facie case could not be rebutted unless the Secretary were able to identify what had caused the child to have a partial brain. It is implausible that Congress would have intended that result.

In seeking to justify its holding in *Koston*, the court of appeals stated that it was its duty to construe the Act as written, even if that construction would (as the Secretary argued) produce absurd consequences. 974 F.2d at 161. Even if the text of the Act seemed unambiguous on the point, a court's duty is not so unyielding. See, *e.g.*, *Public Citizen* v. *United States Dep't of Justice*, 491 U.S. 440, 453-454 (1989); *Church of the Holy Trinity* v. *United States*, 143 U.S. 457, 459 (1892). In fact, however, the term "idiopathic" is susceptible of a far narrower construction than the one adopted by the court of appeals. In such circumstances, the court had a duty to avoid an interpretation of the statutory language that would produce absurd results. *Haggar Co.* v. *Helvering*, 308 U.S. 389, 394 (1940); see also *Public Citizen*, 491 U.S. at 454-455. Because Congress could not have intended to permit compensation in circumstances in which the evidence shows that a preexisting condition, and not the vaccine, caused the child's injury or disability, the court of appeals' construction of the term "idiopathic" should be rejected.

CONCLUSION

The judgment of the court of appeals should be reversed, and the case should be remanded to the court of appeals for review of the judgment of the Court of Federal Claims under the proper legal standards.

Respectfully submitted.

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